§170.315(a)(10) Drug-formulary and preferred drug list checks

2015 Edition CCGs

Version 1.5 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-22-2015
1.1	Added clarification regarding drug formulary files if the Health IT Module is using the NCPDP Formulary and Benefit Standard v3.0.	12-18-2015
1.2	Revised as a result of further analysis of the applicability of the 2015 Edition “amendments” certification criterion (§ 170.315(d)(4)) to health IT capabilities that would not necessarily have any patient data for which a request for an amendment would be relevant.	04-24-2017
1.3	Removal of Amendments (§ 170.315(d)(4)) under Approach 1 in the Privacy and Security section of the table.	05-08-2017
1.4	Updated 'CEHRT Definition' value from "No" to "Yes" to match regulation text.	02-22-2018

1.5	Added clarification for time-limited certification to this criterion per the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule.	06-15-2020

Regulation Text

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§170.315 (a)(10) *Drug-formulary and preferred drug list checks—*

The requirements specified in one of the following paragraphs (that is, paragraphs (a)(10)(i) and (a)(10)(ii) of this section) must be met to satisfy this certification criterion:

(i) *Drug formulary checks.* Automatically check whether a drug formulary exists for a given patient and medication.

(ii) *Preferred drug list checks.* Automatically check whether a preferred drug list exists for a given patient and medication.

Standard(s) Referenced

None

Certification Companion Guide: Drug-formulary and preferred drug list checks

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Unchanged	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(a)(10). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) "paragraph (a)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be presented once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.
- Health IT presented for certification to this criterion would not have to demonstrate the capabilities required by the 2015 Edition "amendments" certification criterion (§ 170.315(d)(4)), unless the health IT is presented for certification to another criterion that requires certification to the 2015 Edition "amendments" criterion under the privacy and security certification framework.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- There is no standard required for this certification criterion. We encourage the industry to accelerate its work on a real-time individual patient-level standard for drug-formulary checking, which we will consider proposing in future rulemaking. [see also 80 FR 62623]
- Health IT needs to demonstrate either the ability to automatically check whether 1) a drug formulary exists or 2) whether a preferred drug list exists, for a given patient and medication.
- ONC–ACBs are permitted to issue certificates for this criterion up until January 1, 2022 to align with the requirements of the CMS Medicaid Promoting Interoperability Program, as this criterion is associated with measures under the Medicaid program that will continue through 2021; after 2021 there will be no further incentives under the Medicaid Promoting Interoperability Program.[see also 84 FR 42592] We have not finalized our proposal to remove the criterion from the CFR but included a provision in § 170.550(m)(1) to only allow ONC–ACBs to issue certificates for this criterion until January 1, 2022. [see also 80 FR 25661]

Paragraph (a)(10)(i)

Technical outcome – The health IT automatically checks for a drug formulary for a given patient and medication.

Clarifications:

- No standard is required for drug formulary checks. However, NCPDP Formulary and Benefit Standard v3.0 is widely implemented today in support of Medicare Part D requirements. Note that drug formulary files should be downloaded and incorporated into the health IT system if using the NCPDP Formulary and Benefit Standard v3.0.
- Health IT will not satisfy this provision if it provides a hyperlink to a patient's drug formulary that a user would have to manually open and navigate. The health IT must perform an automated check for a drug formulary for a specific patient and the medication to be prescribed. [see also 77 FR 54204]
- An internally managed drug formulary is acceptable for the automatic checking. [see also 77 FR 54204]

Paragraph (a)(10)(ii)

Technical outcome – The health IT automatically checks for a preferred drug list for a specific patient and medication to be prescribed.

Clarifications:

- No additional clarifications available.

Content last reviewed on June 22, 2020